REMARKS

In the Office Action dated April 29, 2009, claims 2-10 and 12 were rejected under 35 U.S.C. §112, second paragraph as being indefinite. The Examiner stated the term "only and precisely" in claim 12 is a relative term, and is not defined by the claim, and the Examiner stated the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicants respectfully disagree that the term "only and precisely" is indefinite, in terms of normal English usage, and also disagrees that this term is not adequately defined in the present specification.

The term "only and precisely" is intended to claim the feature that the displayed input fields are specifically configured for entry of specific information relating to a specific clinical study. This is consistent with the commonly understood English definition of "precisely." Moreover, this term is intended to convey the feature that the input fields are not suitable for accepting entry of information other than for the specific clinical study in question. This is consistent with the normal English definition of "only." Therefore, Applicants respectfully submit that the term "only and precisely" is being used consistent with its normal English definition, and would easily be understood in that context by a person of ordinary skill in the art, and therefore it is not even necessary for any further definition to be provided in the specification. Nevertheless, the specification does, in fact, provide further explanation as to the meaning and scope of this term, by describing the type of data entries that are made in accordance with the invention in the displayed input fields. Such information is provided in the present specification at paragraph [0004] at page

2 of the present specification and in paragraph [0017], which bridges pages 5 and 6 of the present specification.

A further basis stated by the Examiner for the rejection under Section 112 is that the Examiner stated he is unsure whether the term "only and precisely" is used to modify the information being entered into the fields, to modify the displayed fields, or to modify a combination of the displayed fields and the data. Claim 12 has been editorially amended to make clear that the term "only and precisely" identifies (modifies) the configuration of the input fields. The Applicants have had the insight to recognize, however, that by appropriately configuring the displayed input fields "only and precisely" for entry of data that is necessary for a specific medical clinical study, this configuration will, in turn, inherently limit and define the data that can actually be entered into the computer via the displayed input fields. Applicants believe this is clear from the existing language of claim 12. Simply because configuring the displayed input fields "only and precisely" as set forth in claim 12 has, in turn, an effect on the data that can be entered into the computer via those input fields, does not render the term "only and precisely" indefinite.

Also, informalities were noted in claims 3 and 6 that served as a further basis for rejecting those claims under Section 112, second paragraph. Those informalities have been corrected.

Therefore, Applicants submit that all claims of the application are in full compliance of all provisions of 35 U.S.C. §112.

Additionally, claim 12 was rejected under 35 U.S.C. §103(a) "as being unpatentable over a piece of paper and a computer."

In substantiating this rejection, the Examiner recited a number of method steps that the Examiner believes are "taught" by a piece of paper. Applicants are unable to follow the Examiner's reasoning, but claim 12 has been editorially amended to make clear that the distribution of the customized input platform program takes place electronically, from the processor in which that input platform is generated. If the Examiner's thought process was that the customized computer platform can be printed out on a piece of paper as program code and then the piece of paper can be physically taken to other computers, this would still require the program code to be entered into each of those other computers, and Applicants submit that although such a procedure might (in theory, but not as a practical approach) be facilitated or implemented by using a piece of paper, such a procedure is not "taught" by a piece of paper.

For similar reasons, Applicants are unable to follow the Examiner's reasoning with regard to the portion of this rejection that the Examiner states can be performed by a general purpose computer. Applicants of course agree that at least portions of the claimed method can be, and are intended to be, implemented by the use of a general purpose computer, but this still requires that such a general purpose computer be either pre-programmed, or instructed to perform the method steps by user entries into the computer, and therefore simply having the knowledge of the functions that can be performed by a general purpose computer in no manner renders the subject matter of claim 12 as being obvious. Even if a customized computer platform can be generated using a general purpose computer, by a person of ordinary skill in the field of computer programming, such a person still needs to be *instructed* or guides as to the contents of such a customized platform, and the

combination of a piece of paper and a general purpose computer does not provide any such instructions, or guidance, much less any motivation.

Evidence of the fact that a piece of paper and a general purpose computer do not render the subject matter of claim 12 obvious is apparent from the manner by which data entry for clinical studies has been conventionally undertaken, as described in the introductory portion of the present specification. Without such customized, uniform input data fields that are used for the entry of all data into a clinical study, the conventional result has been that data are entered from a number of different computer locations in many different ways and according to many different formats, and it is time consuming and expensive to then have to correlate or edit all of these different entry configurations. Aside from the additional time that is necessary to conform all of the different data entry configurations with each other for a particular clinical study, this conventional procedure also has the risk that entered data will be lost if it has been entered in a format that simply cannot be made to conform to the manner by which the data are being used in the clinical study.

For all of these reasons, Applicants respectfully submit that claim 12 would not have been obvious to a person of ordinary skill in the field of designing computer systems for entering data for medical clinical studies, under the provisions of 35 U.S.C. §103(a), based on a piece of paper and a computer.

Claims 4, 10 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Oracle Clinical Research Process Suite, and Califano et al. Claims 2, 3 and 5-8 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of the Oracle Clinical Research Process Suite and Califano et al, further in view of Teshima.

In response to these rejections, the subject matter of claim 2 has been embodied in independent claim 12, and claim 2 accordingly has been cancelled. Therefore, only the rejection of original claim 2 needs to be addressed herein.

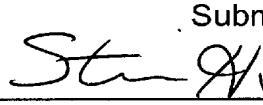
In substantiation of the rejection of original claim 2, the Examiner stated that the Teshima reference teaches "distributing the customized input platform program in a framework of an electronically storable medical data standard." For this purpose, the Examiner cited column 1, lines 53-67. Applicants acknowledge that this passage in the Teshima reference discloses the conventional use of the DICOM standard for the purpose of transmitting *image data*, but Applicants submit that nothing in this passage in Teshima et al, nor elsewhere in that reference, teaches the *non-conventional* use of the DICOM standard for distributing a customized user input platform. Only the present Applicants have had the insight to make use of an electronically storable medical standard, such as the DICOM standard, in this new manner, for the purpose of distributing a customized platform for the purpose of entering data for a clinical study. The conventional use of the DICOM standard for transmitting *image data* does not suggest this use for a completely purpose.

Applicants therefore respectfully submit that none of claim 12 or the claims depending therefrom would have been obvious to a person of ordinary skill in the field of designing computerized systems for entering data in the context of a medical clinical study, under the provisions of 35 U.S.C. §103(a), based on the teachings of the Oracle Clinical Research Process Suite, Califano et al and Teshima et al.

All claims of the application are therefore submitted to be in condition for allowance, and early consideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,



(Reg. 28,982)

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